15. The method of claim 14, wh rein the composition is a solution or emulsion.

C4 Cont

16. The method of claim 14, wherein the composition consists essentially of 2 to 20 units of insulin per 100 g of composition.

17. The method of claim 16, wherein the composition is a solution or emulsion.

REMARKS

Reconsideration of this application is respectfully requested. Claims 5 and 9 have been amended to recite that an effective amount of a composition consisting essentially of insulin is applied. Claim 6 has been amended to clarify that the composition further consists essentially of cosmetically or pharmaceutically acceptable ingredients. Claims 10-17 have been added. Support for new claims 10-17 is found at page 3, lines 26-27, of the specification. Claims 5, 6, and 9-17 are pending and at issue.

Claims 5 and 9 have been rejected under 35 U.S.C. §102(e) as anticipated by Danielov (U.S. Patent No. 5,885,974) and under 35 U.S.C. §102(b) as anticipated by Weiner (U.S. Patent No. 5,200,393).

This rejection is respectfully traversed and reconsideration is respectfully requested.

The formulations disclosed in Danielov include many insulin antagonists, such as glucagon, adrenocorticotropic hormones (ACTH) and thyrotropic hormones (TSH). See Example 1 (col. 31, lines 23, 31, and 39), Example 2 (col. 33, lines 34 and 42), and Example 3 (col. 35, lines 35 and 44). Insulin is an anabolic hormone which decreases blood glucose. In contrast, glucagon increases blood glucose and ACTH and TSH are catabolic hormones.

Claims 5 and 9 as amended exclude ingredients, such as insulin antagonists, which affect the basic and novel characteristics of the recited composition, i.e., its ability to treat the recited indications.

Example 8 of Danielov describes an eye solution. Danielov does not disclose or suggest *topically* applying the solution to the skin or scalp. Danielov also does not disclose the function of the insulin in the solution. Therefore, one of ordinary skill in the art would not have the motivation to topically apply a composition consisting essentially of insulin based on Danielov.

For the foregoing reasons, Danielov does not anticipate claims 5 and 9.

Furthermore, Danielov teaches a product containing 0.1 to 5 μg human insulin per kilogram of product (col. 14, lines 52-54, and col. 15, line 1). 1 milligram of insulin contains 24-28 units of insulin. 0.1-5 microgram of insulin is

qual to 0.0024-0.12 units of insulin. The composition recit d in claims 10-17 includes at least 2 units of insulin per 100 g of composition, i.e., at least 20 units of insulin per kilogram of product. This is at least 1600 times the amount taught in Danielov. Danielov does not disclose or suggest a composition containing at least 2 units of insulin per 100 g of composition.

In fact, Danielov teaches away from such a composition. Danielov states that "[t]he amount and concentration of the bioactive agents in the compositions ... is critical to the ... invention" (col. 8, lines 5-6).

> "[T]he compositions contain the [bioactive] agents in amounts which are similar to those amounts found in normal living organisms with a normal functioning biological information transfer system. Depending upon the precise therapy, the compositions ... contain the bioactive agents in amounts ranging from about those found in such normal living organisms to about two or three times the amount found in normal living organsism." (col. 8, lines 17-27).

Danielov further states that "unusual and non-physiological effects are observed when the same bioactive substance is used in amounts exceeding the physiological level" (col. 3, lines 52-57). Such physiological effects include failure of restoration of the disrupted mechanism (disrupted transfer of biological information) (col. 3, lines 58-67).

Therefore, Danielov teaches away from using significantly more insulin than the amounts specified therein. Accordingly, one of ordinary skill in the art

would not have the motivation to include 1600 times the amount of insulin specified by Danielov in a topical composition.

For the foregoing reasons, Danielov does not anticipate the presently claimed invention.

Weiner discloses a lipid excipient which can be used (1) for topical application, or (2) as a nasal delivery system for peptides, such as calcitonin and insulin. See, for example, Examples 3 and 7, in which calcitonin and insulin were delivered nasally. Weiner does not disclose a topical composition containing insulin.

Furthermore, Weiner does not disclose or suggest a composition for topical application containing at least 2 units of insulin per 100 g of composition as recited in claims 10-17.

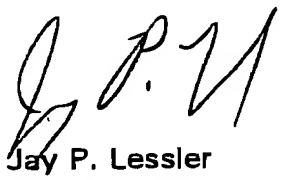
Accordingly, Weiner fails to anticipate the present claimed invention.

For the foregoing reasons, applicants respectfully request withdrawal of this rejection.

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner beli ves could b resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted



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Marked-Up Claims
Accompanying Amendment in response to February 11, 2003 Office Action
For U.S. Serial No. 09/748,466
(Docket No. 3142/1G877-US2)

IN THE CLAIMS:

5. (Thrice Amended) A method of increasing skin firmness and elasticity, reducing lines and wrinkles of skin, improving age spots and clarity of skin, raising ability of skin or scalp to scavenge oxygen free radicals, raising ability of skin or scalp against UV-induced damage, treating aging of skin or scalp, preventing skin or scalp from aging, treating winter itch, or improving secretion of sebaceous and sweat glands comprising:

topically applying an effective amount of a composition consisting essentially of insulin, which can be natural, synthetic, recombinant, human or animal, to the skin or scalp.

6. (Twice Amended) The method of claim 5, wherein said [method further includes using] composition further consists essentially of cosmetically or pharmaceutically acceptable ingredients [to formulate a product of cosmetic or pharmaceutical comprising:

said insulin which can be natural, synthetic, recombinant, human or animal].

9. (Amended) A method of treating aging of skin or scalp or preventing skin or scalp from aging comprising:

topically applying an effective amount of a composition consisting essentially of insulin, which can be natural, synthetic, recombinant, human or animal, to the skin or scalp.